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OSTEOPOROTIC FRACTURE MANAGEMENT

Mechanical torque measurement predicts load to implant cut-out: a biomechanical study investigating DHS® anchorage in femoral heads

Norbert Suhm · Clemens Hengg · Ronald Schwyn · Markus Windolf · Volker Quarz · Markus Hänni

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Abstract
Introduction Bone strength plays an important role in implant anchorage. Bone mineral density (BMD) is used as surrogate parameter to quantify bone strength and to predict implant anchorage. BMD can be measured by means of quantitative computer tomography (QCT) or dual energy X-ray absorptiometry (DXA). These noninvasive methods for BMD measurement are not available pre- or intra-operatively. Instead, the surgeon could determine bone strength by direct mechanical measurement. We have evaluated mechanical torque measurement for (A) its capability to quantify local bone strength and (B) its predictive value towards load at implant cut-out.
Materials and methods Our experimental study was performed using sixteen paired human cadaver proximal femurs. BMD was determined for all specimens by QCT. The torque to breakaway of the cancellous bone structure (peak torque) was measured by means of a mechanical probe at the exact position of subsequent DHS® placement. The fixation strength of the DHS® achieved was assessed by cyclic loading in a stepwise protocol beginning with 1,500 N increasing 500 N every 5,000 cycles until 4,000 N.
Results A highly significant correlation of peak torque with BMD (QCT) was found ($r = 0.902$, $r^2 = 0.814$, $P < 0.001$). Peak torque correlated highly significant with the load at implant cut-out ($r = 0.795$, $P < 0.001$). All specimens with a measured peak torque below 6.79 Nm failed at the first load level of 1,500 N. The specimens with a peak torque above 8.63 Nm survived until the last load level of 4,000 N.
Conclusion Mechanical peak torque measurement is able to quantify bone strength. In an experimental setup, peak torque identifies those specimens that are likely to fail at low load. In clinical routine, implant migration and cut-out depend on several parameters, which are difficult to control, such as fracture type, fracture reduction achieved, and implant position. The predictive value of peak torque towards cut-out in a clinical set-up therefore has to be carefully validated.

Keywords Bone mineral density · Mechanical torque measurement · Osteoporosis · Hip fracture · Implant cut-out

N. Suhm · R. Schwyn · V. Quarz (✉) · M. Hänni
AO Development Institute, Clavadelerstrasse 8,
7270 Davos Platz, Switzerland
e-mail: volker.quarz@aofoundation.org

C. Hengg
Department of Trauma Surgery,
Medical University Innsbruck,
Anichstrasse 35, 6020 Innsbruck, Austria

M. Windolf
AO Research Institute, Clavadelerstrasse 8,
7270 Davos Platz, Switzerland

Introduction

Osteosynthesis using dynamic plate or intramedullary nail devices is the standard method to stabilize proximal femoral fractures [9]. Numerous positive results have been reported, but complications in the use of these implants, including implant cut-out, and migrations, also have been presented [1, 6]. Bone strength plays an important role for implant anchorage [1]. As a result, there is particular concern regarding osteosynthesis' failure, when such implants are used for fracture fixation in osteoporotic bone. If the surgeon could get pre- or intra-operative information on bone strength indicating that implant loosening might develop, then supplementary augmentation could be used [2].

There is a clinical demand for a direct or surrogate measure of bone strength. Parameters that have been applied to quantify bone strength and to predict implant fixation strength include bone mineral density measured by dual energy X-ray absorptiometry [BMD (DXA)] or by quantitative computer tomography [BMD (QCT)]. These methods are non-invasive, but also not available pre- or intra-operatively on a routine basis. Instead, the surgeon could determine bone strength by direct mechanical measurement. Intra-operative measurement of insertion torque was evaluated for the determination of pedicle screw anchorage with uneven results [8, 12].

We have developed a method for standardized mechanical measurement of peak torque to breakaway of the femoral head's trabecular bone (peak torque). It was the goal of this study to evaluate this measurement method for its ability to measure bone strength by correlating peak torque with BMD (QCT) and to verify the predictive value of peak torque towards load at implant cut-out in the proximal femur biomechanically.

Material and methods

Bone specimens

Sixteen paired fresh frozen cadaveric femurs were used for testing. The medians and ranges of age, weight and height of the donors were 73.5 years (range 63.8–94.0 years), 63.5 kg (range 47.0–84.0 kg) and 164 cm (range 148–174 cm), respectively. The use of the human specimens for scientific purpose was approved by the local ethical committee. The bones and adjacent joints did not show any macroscopic pathology, such as lower limb fracture, generalized bone disease or severe arthrosis, which might have interfered with the mechanical properties of the bone. Prior to and in between the different tests, the specimens were stored at-20°C. All specimens were allowed to reach room temperature before testing for 24 h. While defrosting and during testing, the specimens were kept moist.

Mechanical torque measurement

Torque to breakaway of trabecular bone was measured by means of a custom made mechanical probe. It was designed as a wing blade with 7.0 mm outer diameter and 24.0 mm blade length (Fig. 1). Cannulation allowed the insertion over a pre-positioned guide wire. The guide wire was placed in the posterior-inferior quadrant of the femoral head according to the DHS® operation technique using the 135° aiming device. The position of the guide wire was controlled by means of an image intensifier (Arco si 100®, Applicazione Tecnologie Speciali SRL, Pedrengo, Italy) in two planes. The lateral cortex of the femur was opened with the 8.0 mm cannulated spiral drill. Subsequently, the cannulated torque measurement probe was inserted along the guide wire into the femoral head to reach a tip apex distance of 10.0 mm (Fig. 2). The final position of the measurement probe was documented by X-ray in two planes. The guide wire was removed prior to torque measurement in order to exclude any interference with the following measurement process. The peak torque until complete breakaway of the cancellous bone between the wings of the measurement probe (peak torque) was assessed by rotating the probe around its longitudinal axis. The peak torque was recorded by means of a calibrated digital torque meter (HD-100®, HIOS Inc., Akiyama, Japan). The data were processed with MATLAB® Software (The MathWorks, MA, USA).

Measurement of bone mineral density by quantitative computer tomography [BMD (QCT)]

Bone mineral density (QCT) was measured in the femoral head using a routine given by the scanner's manufacturer (DensiScan 1000®, Scanco Medical, Bassersdorf, Switzerland; basis data: acceleration voltage 50 kV at 0.5 mA). Seven CT slices were considered for measurement. The central slice was placed at the largest

Fig. 1 Custom made probe for mechanical measurement of peak torque to breakaway. Central canulation of the probe (*left*) allows insertion over a guide wire. The measurement probe itself comprises three blades that are placed at an angular distance of 120° each. A scale for length measurement (*right*) enables adaptation of the probe to varying length of the femoral neck

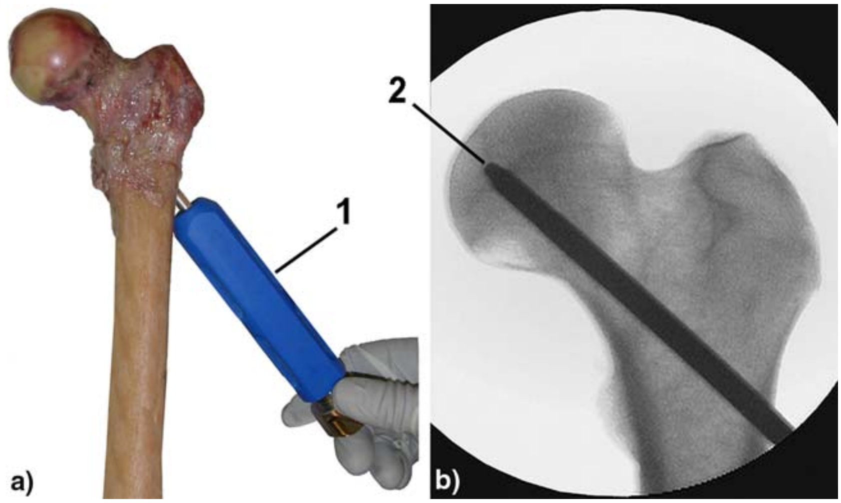

Fig. 2 Test set up for torque measurement. **a** An adjustable handle (*1*) was used to insert the mechanical measurement probe (*2*) to the position previously defined by the guide wire. **b** The final position of the measurement probe (*2*) within the femoral neck and head was documented by image intensifier

diameter of the femoral head and three additional slices were placed in both medial and in lateral direction with 1.0 mm interslice distance. BMD (QCT) was determined from a cancellous bone cylinder of 50% core volume of the resulting femoral head section. CT-data were processed directly into BMD in the unit gram per cubic centimeter (g/cm^3) by the manufacturer's software. The CT scanner was calibrated to the European Forearm Phantom (EFP-060, QRM GmbH, Möhrendorf, Germany) representing hydroxyapatite (HA) densities of 50, 100 and 200 mg HA/cm^3. No soft tissue equivalent was approved for application with this scanner.

Biomechanical testing

For biomechanical testing, the femoral necks were cut perpendicular to the femoral neck axis and 50 mm underneath the joint surface. A DHS® (length 105 mm) was implanted in the exact point of previous torque measurement. Implant position within the femoral head was documented radiographically (Mobilett XP®, Siemens Medical Solutions, Zürich, Switzerland). Each specimen was mounted on a custom made testing jig with the screw axis at a 20° angle to the unidirectional force transmission axis, thus simulating the main force direction acting on the human proximal femur [4]. The specimens were exposed to cyclic loading, which was transmitted by an artificial articulation component in order to decrease the surface pressure on the femoral head. The test jig was placed on an x-y-table to allow for small compensational movements in a horizontal plane. The loading curve introduced into the femoral head was set similar to the forces in human hip joints for the main force axis during normal gait [3]. Six load steps were applied, each one running for 5,000 cycles at 2 Hz. Starting at peak loads of 1,500 N (250% bodyweight for a person of 60 kg), the force was increased by 500 N every 5,000 cycles. Testing was stopped either when cut-out of the implant occurred, or when a total number of 30,000 cycles was reached, applying 4,000 N as the maximum load. Base load was kept at 200 N for all 30,000 cycles. Cut-out of the DHS® was defined as 5.0 mm displacement of the femoral head when compared to the starting position. The amount of displacement was derived from the traverse path of the force application piston. The tests were performed on an MTS 858 Bionix® servo-hydraulic testing machine (MTS Systems Cooperation, Eden Prairie, MN, USA).

Statistical analysis

The peak torque was correlated with BMD (QCT) using the Pearson test for correlation. The relationships were evaluated by linear regression analysis and by analysis of variance (ANOVA). Normal distribution was confirmed for these variables (Shapiro-Wilk test). Peak torque and BMD (QCT) were correlated with the load at cut-out using nonparametric Spearman correlation. For paired comparison of peak torque and BMD (QCT) data of right/left specimens the Paired-samples t test was applied. Statistical tests were considered significant at levels of P values ≤ 0.05, ≤ 0.01 and ≤ 0.001.

Data were collected in Microsoft® Office Excel tables (Microsoft Corporation, Redmond, USA) and transferred into SPSS® Software for the statistical analysis (Version 14.01, SPSS Inc., Chicago, USA).

Results

Measurement of peak torque and BMD

The specimens examined in this study covered a wide range of BMD (QCT): 0.2–0.51 g/cm^3. The peak torque was found in a range from 3.72 to 12.54 Nm. Comparison of peak torque and BMD (QCT) values in paired specimens did not reveal a significant difference (peak torque: $P = 0.576$, BMD (QCT): $P = 0.542$). Complete data of peak torque and BMD (QCT) is given in Table 1.

Relationship of peak torque and BMD

A high correlation of peak torque with BMD (QCT) was found ($r = 0.902$, $P < 0.001$). Accordingly, there was a high linear relationship between peak torque and BMD (QCT) with $r^2 = 0.814$, $P < 0.001$ (Fig. 3).

Implant cut-out under biomechanical testing

The DHS® cut-out in all specimens under the cyclic loading.

The peak torque measured correlated significantly with the load at cut-out ($r = 0.795$, $P < 0.001$). Considering the relationship in detail, all specimens with a measured peak torque below 6.79 Nm cut-out at a load of 1,500 N (first load step). All specimens with a peak torque above 8.63 Nm survived until 4,000 N (last load step) (Fig. 4). BMD (QCT) also correlated significantly with the load at cut-out ($r = 0.845$, $P < 0.001$).

Table 1 Peak torque, BMD (QCT) and load at cut-out found for the specimens ($n = 16$)

	Peak torque (Nm)	BMD (QCT) (g/cm^3)	Load (N)
Sample			
1 Right	7.14	0.30	2,000
1 Left	7.55	0.34	2,000
2 Right	8.63	0.44	2,000
2 Left	12.54	0.42	3,000
3 Right	7.32	0.31	1,500
3 Left	7.37	0.30	3,000
4 Right	5.43	0.29	1,500
4 Left	3.72	0.26	1,500
5 Right	8.51	0.36	2,500
5 Left	6.79	0.38	3,000
6 Right	12.27	0.51	4,000
6 Left	12.41	0.48	4,000
7 Right	5.90	0.29	1,500
7 Left	7.49	0.30	2,500
8 Right	3.90	0.20	1,500
8 Left	4.23	0.27	1,500
Mean	7.58	0.34	–
Standard deviation	2.83	0.09	–
Range	8.82	0.31	2,500
Minimum	3.72	0.20	1,500
Maximum	12.54	0.51	4,000
Median	7.35	0.30	2,000

Peak torque peak torque to breakaway of the trabecular bone during in situ testing, *BMD (QCT)* bone mineral density measured by quantitative computer tomography, *Load* load at cut-out under biomechanical testing

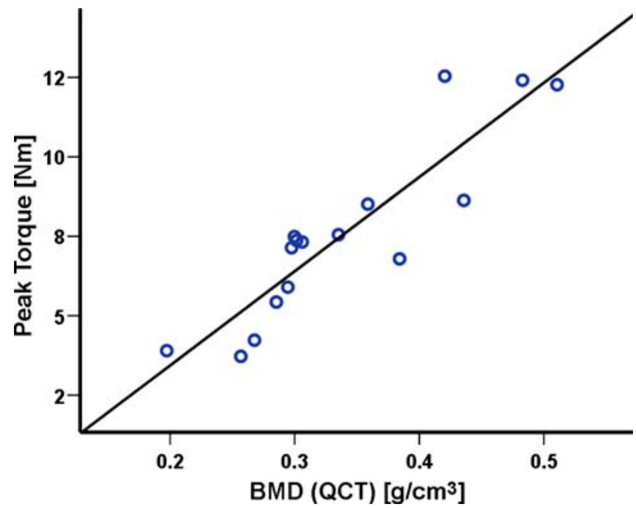

Fig. 3 Scatter plot of peak torque and BMD (QCT). The graph demonstrates a high correlation ($r = 0.902$, $P < 0.001$) and linear relationship ($r = 0.814$, $P < 0.001$) of peak torque with BMD (QCT) over a wide range of BMD values

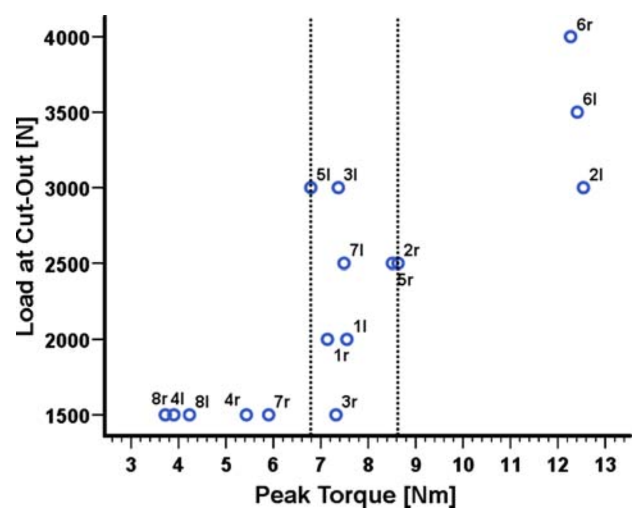

Fig. 4 Scatter plot of peak torque with load at cut-out. Peak torque can nicely separate those specimens that failed at low load (*left*) from such specimen which survived up to 4,000 N (*right*)

Discussion

The insertional torque has been used to predict pedicle screw fixation strength in vitro [14, 15, 18] and in vivo [10, 11, 13]. This method has limitations as the measurement of screw insertion torque is based on the subjectively defined end point of maximum insertional torque [12]. Measurement of peak torque to breakaway of trabecular bone with our dedicated probe has to be looked upon as a superior method, as it objectively measures the resistance of the trabecular bone against complete destruction.

Peak torque is a reliable parameter to quantify trabecular bone strength

This can be concluded from a high correlation we found between peak torque and BMD (QCT) over a wide range of BMD values. Our finding compares well with a biomechanical study that found a correlation between insertional torque of pedicle screws and BMD (QCT) [12].

Bone mineral density (QCT) is unique in describing bone strength, because it provides a 3-dimensional distribution of bone mineral [5]. Accurate measurements of bone mass and 3D orientation have been demonstrated to explain 80 to 90% of the variance in the mechanical behaviour of trabecular bone volumes (Goldstein S. Bone Quality: A Biomechanical Perspective. In: Bone Quality: What Is It And Can We Measure It? A Scientific Meeting. The American Society for Bone and Mineral Research, Bethesda, MD, USA, May 2–3, 2005).

In clinical routine—however, peak torque would be superior to BMD (QCT) as a parameter to quantify bone strength. Like QCT, the proposed peak torque measurement provides information on the exact site of implant anchorage within the femoral head. As our measurement method was especially designed for intra-operative application it would be available to the surgeon, whereas QCT is not available pre- or intra-operatively on a routine basis.

Peak torque was able to predict load to cut-out in our experimental setting

Specimens, which failed at low loads could be identified as well as such specimens which bore high loads. The use of isolated femoral heads in a biomechanical test set-up allowed us to investigate the sole relationship between the strength of cancellous bone and the risk of implant cut-out.

In spinal surgery, the predictive value of pedicle screw insertional torque towards pedicle screw fixation strength was examined. A correlation was found between insertion torque and pullout force [15], between insertional torque and number of cycles to ultimate pedicles screw pullout [18], and the maximum insertion torque and screw pullout force [12]. However, the correlation between peak insertional torque to pullout strength was found to be low by Reitman [14]. Futhermore, a sole validity of pedicle screw insertion torque for prediction of mechanical failure could not be shown in a clinical set-up [10, 11, 13].

To our knowledge, no study was published describing the use of a mechanical parameter for the assessment of implant anchorage within the femoral head. The relevance of bone strength described by BMD for hip screw fixation was shown by push-out and pullout tests in vitro [7, 16]. Considering osteosynthesis of femoral fractures in vivo, it is the type of fracture, quality of fracture reduction achieved and implant position that influences the risk for implant failure aside from bone strength [1, 6, 7, 9, 17]. Intra-operative measurement of peak torque to breakaway is therefore not meant to predict failed osteosynthesis on its own. Instead, the hypothesis that intra-operative measurement of peak torque at the proximal femur is beneficial to the surgeon to judge the stability of his construct needs careful clinical validation.

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